K133074

# MEGA AND SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter
## 510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

### GENERAL INFORMATION


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| Submitter's name and address: | Datascope Corp.<br>15 Law Drive<br>Fairfield, NJ 07004 |
| Contact person and telephone number: | Linda Slutzky<br>Regulatory Affairs Specialist I |
| Phone: | (973) 709-7973 |
| Fax: | (973) 807-9210 |
| Email: | linda.slutzky@maquet.com |
| Date prepared: | November 8, 2013 |


### DEVICE INFORMATION:

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|---|---|
| Trade Name: | MEGA and SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories |
| Common/Generic Name: | Intra-Aortic Balloon (IAB) Catheter |
| Classification Name: | System, Balloon, Intra-Aortic & Control |
| Regulation Number: | 21 CFR 870.3535 |
| Product Code: | DSP |

### PREDICATE DEVICE INFORMATION:

The enhanced 8Fr. Introducer Set is substantially equivalent to the 8Fr. Introducer Set packaged in the MEGA (K091449) and SENSATION PLUS (K112327) 8Fr. 50cc Intra-Aortic Balloon (IAB) Catheters and Accessories predicate devices.

### DEVICE DESCRIPTION AND INTENDED USE:

The 8Fr. Introducer Set is comprised of an Introducer Sheath and Introducer Dilator for percutaneous insertion of the MEGA & SENSATION PLUS 8Fr. 50cc IABs.

The flexible high density polyethylene (HDPE) dilator is inserted through and twist locked into the 8Fr. introducer sheath for insertion over a guide wire for percutaneous access to the femoral artery.

The dilator is then removed from the sheath after which the 8Fr 50cc Intra-aortic Balloon (IAB) Catheter is inserted over a guide wire and through the 8Fr introducer sheath for placement within the thoracic aorta for counterpulsation therapy. The introducer sheath is comprised of a hub housing that includes an integral hemostasis valve to prevent bleeding about the IAB catheter and a sheath tube comprised of a flat coiled stainless wire between a layer of PTFE and Pebax for reinforcement to provide kink resistance within the vasculature.

The intra-aortic balloon is a cardiac assist device. It supports the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work. Coronary perfusion is increased by augmenting blood pressure during the diastolic phase of the cardiac cycle. The resulting increase in aortic pressure promotes more blood flow through the coronary arteries. Left ventricular work is thus reduced by decreasing aortic end-diastolic pressure and reducing resistance to ventricular ejection, resulting in a decrease in blood pressure during the systolic phase of the cardiac cycle. These beneficial effects are caused by the inflation and deflation of the intra-aortic balloon (IAB) Catheter in the patient's descending aorta.

The balloon's inflation and deflation must be properly synchronized with the cardiac cycle. IAB Catheter inflation is initiated at the onset of diastole at the dicrotic notch, and remains inflated through diastole. The IAB Catheter is then deflated at, or just prior to the onset of systole. The IAB Catheter then remains deflated throughout systole. Hence the therapy is also referred to as counterpulsation.

## TECHNOLOGICAL CHARACTERISTICS:

The enhanced 8Fr. Introducer Set is substantially equivalent to the 8Fr. Introducer Set packaged in the MEGA (K091449) and SENSATION PLUS (K112327) 8Fr. 50cc Intra-Aortic Balloon (IAB) Catheters and Accessories predicate devices. The enhanced 8Fr. Introducer Set and the predicate devices have the following similarities:

- the same intended use,
- the same operating principles,
- incorporates the same raw materials,
- incorporates the same basic design,
- sterilized using the same materials and processes,
- the same packaging.

The differences between the enhanced 8Fr. Introducer Set and the predicate Introducer Set for use with the MEGA (K091449) and SENSATION PLUS (K112327) 8Fr. 50cc Intra-Aortic Balloon (IAB) Catheters and Accessories are dimensional changes only. The minor dimensional changes are an increase to the Reinforced Sheath's tip diameter, tube inner diameter and outer diameter and to the Sheath Dilator's outer diameter.

## NON-CLINICAL TESTS:

The enhanced 8Fr. Introducer Set complies with the voluntary standards identified in Section 3 of this submission. Datascope Corp. development process required that the following activities be completed during the development of the enhanced 8Fr. Introducer Set:

- Biocompatibility
- Insertion – Skinline to Artery
- Introducer Set Verification
- Package Performance
- Product Stability
- Sterilization

After review of the Risk Management Plan, there were no new risks identified with this modification to the enhanced 8Fr. Introducer Set. We determined that these tests demonstrate that this device modification is as safe and effective as the predicate devices.

## CLINICAL TESTS:

There was no clinical evaluation of the modified device.

## Conclusion:

Based upon the information submitted in this Special 510(k) premarket notification, the enhanced 8Fr. Introducer Set is substantially equivalent to the currently marketed 8Fr. Introducer Set packaged with the MEGA (K091449) and SENSATION PLUS (K112327) 8Fr. 50cc Intra-Aortic Balloon (IAB) Catheters and Accessories. The enhanced 8Fr. Introducer Set is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The design verification and validation testing established that the enhanced 8Fr. Introducer Set is safe and effective and performs as well as the predicate devices. These modifications will not impact the safety and effectiveness of the enhanced 8Fr. Introducer Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Datascope Corp.
Linda Slutzky
Regulatory Affairs Specialist
15 Law Drive
Fairfield, NJ 07004

Re: K133074
Trade/Device Name: MEGA and SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories
Regulation Number: 21CRF 870.3535
Regulation Name: Intra-Aortic Balloon Catheters (IAB)
Regulatory Class: Class III
Product Code: DSP
Dated: November 8, 2013
Received: November 12, 2013

Dear Ms. Slutzky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications For Use

**510(k) Number (if known):** K133074

**Device Name:** MEGA and SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories

**Indications For Use:** The MEGA and SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories have the following indications for use:

- Refractory Unstable Angina.
- Impending Infarction.
- Acute Myocardial Infarction.
- Refractory Ventricular Failure.
- Complications of Acute MI (ie. Acute MR or VSD or papillary muscle rupture)
- Cardiogenic Shock.
- Support for diagnostic, percutaneous revascularization and interventional procedures.
- Ischemia related intractable ventricular arrhythmias.
- Septic Shock.
- Intraoperative pulsatile flow generation.
- Weaning from cardiopulmonary bypass.
- Cardiac support for non-cardiac surgery.
- Prophylactic support in preparation for cardiac surgery.
- Post-surgical myocardial dysfunction/low cardiac output syndrome.
- Myocardial Contusion.
- Mechanical bridge to other assist devices.
- Cardiac support following correction of anatomical defects

Prescription Use __X__ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner